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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,248	04/26/2007	Simon W. Bayloff	JJM5033USPCT	6950

27777 7590 08/11/2008
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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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08/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,248	Applicant(s) BAYLOFF ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment submitted 12 May 2008 has been received. Claims 7 and 8 have been canceled. Claim 16 has been added. Claims 1-6 and 9-16 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 and 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing with respect to the relationship between the absorbent plug and the diagnostic test reagent. Line 2 recites that the diagnostic test reagent is located in or around the absorbent plug, however, the wherein clause recites that the diagnostic test reagent is in or on an annular diagnostic strip extending radially around the inside of the cap. How could the same diagnostic test reagent be in two different places. What is the relationship between the absorbent plug and the annular diagnostic strip?

The same problem is noted for claim 16.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3-5 and 11-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berke et al (US 5,084,245).

Berke discloses a device comprising a base component (i.e. cup-shaped body) on which a sample sensitive element is mounted and a guide member that is normally mounted on the base component in covering relationship to the reactive element. Berke teaches at least one diagnostic test reagent provided on porous capture elements 42 and 44. See column 8, lines 18-38. Even though Berke does not specifically teach an annular diagnostic strip extending radially around the inside of the cap, Berke does teach that the test reagents are located on the absorbent plug, and since the location of the test reagents in the instant claims are vague, Berke is seen to anticipate or make obvious the claimed invention.

With regard to claims 3 and 4, the base component and the guide member include means which holds the base component and the guide member together. The holding means may comprise a well in the base component and a complementarily shaped projection on the guide member. The projection is normally received in the well

and held in place there by frictional engagement and/or snap-fit mechanical engagement. See column 2, line 59 through column 3, line 3.

With regard to claim 5, Berke teaches a vent for venting air from the well in the base component. See column 7, lines 15-21.

With regard to claim 11, Berke teaches a prefilter mounted on the distal end of the guide member and is in close capillary contact with the sample sensitive element of the cap. When the cap and the guide member are assembled, the prefilter is seen to be part of the cap. See column 9, lines 14-39.

With regard to claim 12, Berke discloses a flow director, 40, which may be transparent to indicate when the diagnostic test reagent has been wetted by an analyte solution by enabling a viewing of a change in color in membranes 42 and 44. See column 14, lines 28-38.

With regard to claim 13, Berke teaches an enzyme assay. See column 8, lines 17-26.

With regard to claim 14, Berke teaches antibodies as binding partners. See column 9, lines 52-66.

With regard to claim 15, Berke teaches the detection of multiple analytes. See column 9, lines 52-66.

6. Claims 6, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berke et al in view of Sayles (US 5,429,804).

See the discussion of Berke above. Berke differs from the instant claim in failing to teach that the cap is at least partially transparent.

Sayles discloses a test device having a lower cup for receiving a fluid specimen and a lid containing a chamber having one or more reagent strips protruding therefrom. The lid is attachable to the cup and results can be read through a transparent area of the lid. See abstract. Sayles also teaches that on the rim, around the transparent area, can be written a plurality of indicia to indicate the particular test being done in the chamber segment below. See column 2, lines 46-50.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the base component of Berke such that it has at least a transparent area because such material is well known in the art. A skilled artisan would have had a reasonable expectation of success in including a transparent area in the device of Berke because Berke teaches that his device may be made from a variety of material including plastic or glass, etc (see Berke, column 7, lines 37-44). It also would have been obvious to include different indicia corresponding to different regions of assays on the cap such as taught by Sayles because both Sayles and Berke teaches the possible detection of multiple analytes and indicia would be required to identify them.

7. Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as obvious over Berke.

See the discussion of Berke above. Even though Berke does not specifically discloses the dimensions of the cap nor does Berke recites the uncompressed volume of the absorbent material, these limitations are nothing more than routine optimization in

the art. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation."

Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims are for any particular purpose or solve any stated problem and the prior art teaches that a variety of different commercially available absorbent may be use and that the specific selection often vary according to the samples being analyzed, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the art.

Response to Arguments

8. Applicant's arguments filed 12 May 2008 have been fully considered but they are not persuasive.

Applicant argues that Berke does not anticipate the instant invention because Berke fails to teach annular diagnostic strip extending radially around the inside of the cap.

This argument is not persuasive. Berke teaches diagnostic test reagents disposed in capture elements 42 and 44 that are in turn disposed on an absorbent pad 46. A skilled artisan can clearly see that the flow director 40 and the absorbent pad 46 are both configured to be on the inside of the cap assembly. Because claim 1 is unclear with respect to the annular diagnostic strip it cannot be determined if the diagnostic test reagent is located *in* or *around* the absorbent plug. If the diagnostic test reagent is located in the absorbent plug then Berke meets this limitation. Furthermore, claim 16 recites that the diagnostic test reagent is located on diagnostic sheet extending transversely across the inside as well as being in the absorbent plug. Thus, Berke is seen to anticipate this limitation as well.

The arguments with respect to claims 2 , 9, 6 and 10 are hinged upon the Berke reference, thus their response is addressed with respect the Berke reference above.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2002/0085953

US 5,800,779

US 6,083,460

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
August 4, 2008